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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/084,837 05/26/98 LUTTICKEN

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EXAMINER

MOSHER, M

ART UNIT

PAPER NUMBER

1648

18

DATE MAILED:

07/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/084,837

Applicant(s)

Lutticken et al

Examiner

Mosher

Group Art Unit

1648



☒ Responsive to communication(s) filed on 4/14/00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 12, 13, 16-21, 32-39 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 12, 13, 16-21, 32-39 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1648

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Mosher.

Interference No. I104460 has been terminated by a decision adverse to applicant. *Ex parte* prosecution is resumed.

Claims 1-4, 6-10, 15, and 24-31 stand finally disposed of in accordance with 37 CFR 1.663.

The indicated allowability of claims 12, 13, and 16-21 is withdrawn in view of newly discovered reference(s). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 12 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mundt (4/16/1997). Mundt et al teaches that IBDV VP5 antibodies are found in sera from chicks which have been immunized with an IBDV live vaccine, thereby detecting the presence of IBDV infection in the chicks. This appears to meet each and every limitation of the method claims. If this does not anticipate the claimed method, then it clearly suggests the claimed method, since it teaches that chickens infected with live IBDV develop a detectable immune response to VP5, and one would have reasonably expected success in detecting a similar response in birds infected with other types of IBDV.

Claims 13 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mundt. These claims differ from the publication in that they require a solid phase, or in that they involve detection of antigen using antibody rather than detection of antibody using antigen. However, use of solid-phase immunoassays is conventional, therefore claim 13 is seen as obvious over the publication. In addition, since Mundt teaches that chickens infected with a live IBDV vaccine virus develop an immune response against VP5, it follows that VP5 expression occurs in IBDV-infected chickens, and therefore suggests detection of VP5 antigen in infected chickens. Therefore, the diagnostic method involving detection of VP5 antigen using VP5 antibody is also seen as obvious, absent unexpected results.

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Claims 33-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the lost interference count, optionally in view of any or all of Lewin, Culver et al, Roizman, DeWind et al, and Keeler. The lost interference count qualifies as prior art under 35 USC 102(g).

The interference count requires a virus which is not able to produce VP5 as a result of a mutation in the VP5 gene. Newly added claims 33-39 differ from the count in specifying alteration of at least two nucleotides in the VP5 start codon, and in requiring additional stop codons in the 5' end of the VP5 gene. However, it is well known in the art of genetics that single base mutations are "leaky" and revertible, see as evidence the textbook by Lewin. One of ordinary skill in the art of genetics and virology would have been aware that a virus with multiple nucleotide changes would be less likely to revert to the undesired wild-type VP5 coding sequence. Alteration of more than one nucleotide to remove a start codon has been known for years in the virology art, see for example Culver et al (1989). Therefore altering more than one base in the start codon would have been obvious to one of ordinary skill in the art, as a known form of mutation preventing expression of a protein, with an obvious advantage of reducing the probability of reversion. In addition, the use of multi-frame stop codons to prevent expression of an unwanted gene is also commonplace in the virology art, see as evidence examples in Roizman 5328688, column 16, lines 16-20; DeWind et al WO 91/02795, the passage spanning pages 6-7; Keeler 5279965, col 3 line 52 to col 4 line 8. Therefore, since the lost count requires a virus which is not able to produce VP5 as a result of a mutation in the VP5 gene, it would have been obvious to choose forms of mutation which were known to prevent production of a protein, such as changing

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two nucleotides in the start codon and introducing a three-frame set of stop codons. The invention as a whole is therefore prima facie obvious, absent unexpected results. Applicant's observation of little or no reversion is a result expected from the use of these known forms of mutation, not an unexpected advantage.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 10, 2000


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1648
1600